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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,444	12/21/2001	Kang P. Lee	ASPEN 112 US	1737

20350 7590 06/16/2005

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,444

Applicant(s)

LEE ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 17-44 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 and 17-44 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of the remarks filed on 03/25/05. Accordingly claims 1 and 17-44 remain pending.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 17-19, 22-25, 29-30, 32-39 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by, or alternatively under 35 U.S.C. 103 (a) as being unpatentable over Berg et al (WO 9501135).

For a disclosure of Berg et al see Office Action of 12/27/04.

Claims 1, 17-18 and 22-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al in view of Manning et al (5,981,474).

For a disclosure of Berg et al and Manning et al see Office Action of 12/27/04.

Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al in view of Rouanet et al (5,864,923).

For a disclosure of Berg et al and Rouanet et al see Office Action of 12/27/04.

Note:

The Office Action of 12/27/04 appears to have a typing error. Claims 20-21 and 26-28 were not meant to be included in the rejection under 35 U.S.C. 102(b) as being anticipated by, or alternatively under 35 U.S.C. 103 (a) as being unpatentable over Berg et al (WO 9501135). Berg et al lacks specific disclosure on surface area and density of the aerogel particles and also therapeutic agents such as insulin, methadone and naltrexone, and thus claims 20-21 and 26-28 are not anticipated by Berg et al.

Response to Arguments

Applicant's arguments filed on 03/25/05 have been fully considered but they are not persuasive.

Applicant argues that Berg et al does not teach or suggest a dry powder comprising a therapeutic agent capable of reaching alveoli. This is not persuasive because 1) to meet the limitations of product claims, all that prior art needs to do is meet the components of the product and is not required to teach the function or property of the formulation or product. Here in claim 1, the limitations examined are dry powders comprising a therapeutically effective amount of a therapeutic agent in aerogel particles. Berg et al is clearly teaching all of the said limitations. The aerogels include therapeutic agents, they are used as a drug delivery system and they may be in a dry form.

Although not required to meet the limitation of alveoli delivery, Berg does that. The particles are said to have a diameter of less than 5 microns, which are suitable for reaching the alveoli region. The aerogel formulations are also said to be used in an

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aerosol delivery. Although Berg's preferred embodiment appears to be diagnostics, it does in depth teach and disclose therapeutic delivery and treatments using medicaments. Preferred embodiments do not negate a broad disclosure.

Applicant states that Berg's aerogel particles loaded with "gas" and thus are not suitable for air filled portions of the lungs. This is correct, however, the recited part of page 12, lines 7-29, reads "any biocompatible gas MAY be present in the pores of organic aerogels used as ultrasound contrast agents". It is noted that 1) The said gases MAY be present (means it is an optional addition), and 2) The aerogels may contain gas only in contrast agents, and not in therapeutic agents.

Applicant's arguments repeatedly refer to alveoli delivery. This is not commensurate with the scope of the instant claims. As mentioned above 1) product claims are examined based on their components, and 2) Berg et al does teach aerosol formulations of aerogels with particle size of less than 5 microns.

Applicant argues that "Manning et al fail to provide any teaching or suggestion of the subject matter in rejected claims 31, 40-43. Because these claims were not included in the alleged rejection based upon Berg et al alone, Applicants respectfully submit that these claims are not properly included in the instant rejection because of a failure to meet the standards set forth at MPEP 2143.03 and in the cases cited therein because not all claim limitations are taught at least with respect to claims 31 and 40-43".

This statement is incorrect or at the least confusing, because claims 31 and 40-43 are rejected under an obviousness rejection and not by anticipation. These claims include limitations that are taught by Berg and limitations that are disclosed by Manning.

The combination of the said prior art references teach all the limitations and not each prior art document individually.

Berg teaches method of preparing the aerogels. The aerogels are said to be made from polymer components such as peptide polyamides, hyaluronic acid, chitosan, chitin, collagen, gelatin, albumin and starch (see page 6). The polymer is a gel forming polymer. The aerogels may be loaded with the medicament, which may be CNS agent, diuretics, cardiovascular drugs, hormones, drugs acting on the blood, etc. Manning teaches particles for delivery made by supercritical drying and where the formulations can be for immediate release or slow release.

Applicant argues that Rouanet teaches various aerogel properties without any mention or suggest of anything related to alveolar delivery of therapeutic agents. Again this argument is not commensurate with the scope of rejections. Rouanet was a supporting prior art to Berg et al's disclosure of aerogels. What Berg was missing (namely suitable aerogel density and surface area) was disclosed by Rouanet. Claims 20-21 are composition claims and the combined references teach all their limitations.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

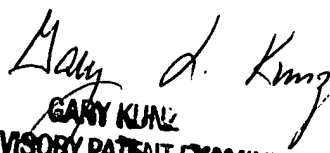
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian
June 10, 2005



GARY KUNZ
SUPERVISORY PATENT EXAMINER
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